AMINOSYN- isoleucine, leucine, lysine acetate, methionine, phenylalanine, threonine, tryptophan, valine, alanine, arginine, histidine, proline, serine, tyrosine and glycine injection, solution
Hospira, Inc.

AMINOSYN®-HBC 7%

Sulfite-Free

AN AMINO ACID INJECTION *— HIGH BRANCHED CHAIN*

Flexible Plastic Container

R_x only

DESCRIPTION

Aminosyn®-HBC 7%, Sulfite-Free, (an amino acid injection high branched chain) is a sterile, nonpyrogenic, hypertonic solution for intravenous infusion. Aminosyn-HBC 7% is oxygen sensitive. The solution contains the following crystalline amino acids:

Essential Amino Acids (mg/100 mL)	
Isoleucine	789
Leucine	1576
Lysine (acetate)*	265
Methionine	206
Phenylalanine	228
Threonine	272
Tryptophan	88
Valine	789
Nonessential Amino Acids (mg/100 mL)	
Alanine	660
Arginine	507
Histidine**	154
Proline	448
Serine	221
Tyrosine	33
Glycine	660
*Amount cited is for lysine alone and does not include the acetate salt.	
**Histidine is considered essential for patients in renal failure.	

Crystalline Amino Acids (g/100 mL)	7
Branched Chain Amino Acids (g/100 mL)	3.2
Nitrogen (approx. g/100 mL)	1.12
Acetate ($C_2H_3O_2^-$)[a] (mEq/Liter)	71[a]
Osmolarity (mOsmol/liter)	623
pH[b] (Range)	5.2 (4.5 to 6.0)
[a]Includes acetate from acetic acid used in processing and from lysine acetate.	

[b]May contain hydrochloric acid for pH adjustment.

The formulas for the individual amino acids present in Aminosyn-HBC 7% are as follows:

Essential Amino Acids	
Isoleucine, USP	$C_6H_{13}NO_2$
Leucine, USP	$C_6H_{13}NO_2$
Lysine Acetate, USP	$C_6H_{14}N_2O_2 \cdot CH_3COOH$
Methionine, USP	$C_5H_{11}NO_2S$
Phenylalanine, USP	$C_9H_{11}NO_2$
Threonine, USP	$C_4H_9NO_3$
Tryptophan, USP	$C_{11}H_{12}N_2O_2$
Valine, USP	$C_5H_{11}NO_2$

Nonessential Amino Acids	
Alanine, USP	$C_3H_7NO_2$
Arginine, USP	$C_6H_{14}N_4O_2$
Histidine, USP	$C_6H_9N_3O_2$
Proline, USP	$C_5H_9NO_2$
Serine, USP	$C_3H_7NO_3$
Tyrosine, USP	$C_9H_{11}NO_3$
Glycine, USP	$C_2H_5NO_2$

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly.

Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

Aminosyn-HBC 7%, Sulfite-Free, (an amino acid injection — high branched chain) provides a mixture of biologically utilizable essential and nonessential crystalline amino acids in concentrated form for protein synthesis. The solution contains a high (45%) concentration of the branched chain amino acids (isoleucine, leucine and valine) relative to other general purpose amino acid injections. Aminosyn-HBC 7%, when mixed with a concentrated source of calories such as hypertonic dextrose, supplemented with appropriate electrolytes, vitamins and trace metals and infused by central vein with or without fat emulsion, provides total parenteral nutrition (TPN) for the severely compromised patient.

Aminosyn-HBC 7% may also be administered peripherally with minimal caloric supplementation in order to conserve lean body mass in the well-nourished, mildly catabolic patient.

A high concentration of the branched chain amino acids is present in Aminosyn-HBC 7% because these amino acids have been reported to be metabolically active in the compromised patient.

The acetate content of the solution, under conditions of parenteral nutrition, would not be expected to affect acid-base status adversely when renal and respiratory functions are normal; confirmatory

clinical/experimental evidence is not available. The amount of sodium present is not clinically significant. The concentration of chloride present is typical for TPN regimens.

INDICATIONS AND USAGE

Parenteral nutrition with Aminosyn-HBC 7%, Sulfite-Free, (an amino acid injection — high branched chain) is indicated to prevent nitrogen loss or treat negative nitrogen balance in adults where (1) the alimentary tract, by the oral, gastrostomy, or jejunostomy route, cannot or should not be used, or adequate protein intake is not feasible by these routes; (2) gastrointestinal absorption of protein is impaired; or (3) nitrogen homeostasis is substantially impaired as with severe trauma or sepsis. Dosage, route of administration and concomitant infusion of nonprotein calories are dependent on various factors, such as nutritional and metabolic status of the patient, anticipated duration of parenteral nutrition support, and vein tolerance. See ***DOSAGE AND ADMINISTRATION*** for additional information.

Central Venous Nutrition: Central venous infusion should be considered when amino acid solutions are to be admixed with hypertonic dextrose to promote protein synthesis in hypercatabolic or severely depleted patients, or those requiring long-term parenteral nutrition. See **SPECIAL PRECAUTIONS FOR CENTRAL INFUSIONS**.

Peripheral Parenteral Nutrition: For moderately catabolic or depleted patients in whom the central venous route is not indicated, diluted amino acid solutions with minimal caloric supplementation may be infused by peripheral vein, supplemented, if desired, with fat emulsion.

CONTRAINDICATIONS

Aminosyn-HBC 7%, Sulfite-Free, (an amino acid injection — high branched chain) is contraindicated in patients with anuria, hepatic coma, inborn errors of amino acid metabolism (especially those involving branched chain amino acid metabolism such as Maple Syrup Urine Disease and Isovaleric Acidemia), severe or uncorrected electrolyte or acid-base imbalance, hyperammonemia or other disorders involving impaired nitrogen utilization, or hypersensitivity to one or more amino acids present in the solution.

WARNINGS

Safe, effective use of parenteral nutrition requires a knowledge of nutrition as well as clinical expertise in recognition and treatment of the complications which can occur. **Frequent evaluation and laboratory determinations are necessary for proper monitoring of parenteral nutrition.** Studies should include blood sugar, serum proteins, kidney and liver function tests, electrolytes, hemogram, carbon dioxide content, serum osmolarities, blood cultures, and blood ammonia levels.

Administration of amino acids in the presence of impaired renal function or gastrointestinal bleeding may augment an already elevated blood urea nitrogen. Patients with azotemia from any cause should not be infused with amino acids without regard to total nitrogen intake.

Administration of amino acid solutions that have not been specifically formulated to treat patients with hepatic insufficiency may result in plasma amino acid imbalances, hyperammonemia, prerenal azotemia, stupor and coma.

Conservative doses of amino acids should be given, dictated by the nutritional status of the patient. Should symptoms of hyperammonemia develop, amino acid administration should be discontinued and the patient's clinical status re-evaluated.

Administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional

to the electrolyte concentrations of the solutions.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

Special care must be taken when administering hypertonic glucose to provide calories in diabetic or prediabetic patients.

Do not withdraw venous blood for blood chemistries through the peripheral infusion site, as interference with estimations of nitrogen-containing substances may occur.

Intravenously administered amino acids should be used with caution in patients with history of renal disease, pulmonary disease, or with cardiac insufficiency so as to avoid excessive fluid accumulation.

The effect of infusion of amino acids, without dextrose, upon carbohydrate metabolism of children is not known at this time.

Nitrogen intake should be carefully monitored in patients with impaired renal function.

Aminosyn-HBC 7%, Sulfite -Free, (an amino acid injection — high branched chain) contains no added phosphorus. Patients, especially those with hypophosphatemia, may require the addition of phosphate. To prevent hypocalcemia, calcium supplementation should always accompany phosphate administration. To assure adequate intake, serum levels should be monitored frequently.

For long-term total nutrition, or if a patient has inadequate fat stores, it is essential to provide adequate exogenous calories concurrently with the amino acids. Concentrated dextrose solutions are an effective source of such calories. Such strongly hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cava.

Aminosyn-HBC contains no more than 25 mcg/L of aluminum.

SPECIAL PRECAUTIONS FOR

CENTRAL INFUSIONS

ADMINISTRATION BY CENTRAL VENOUS CATHETER SHOULD BE USED ONLY BY THOSE FAMILIAR WITH THIS TECHNIQUE AND ITS COMPLICATIONS.

Central vein infusion (with added concentrated carbohydrate solutions) of amino acid solutions requires a knowledge of nutrition as well as clinical expertise in recognition and treatment of complications. Attention must be given to solution preparation, administration and patient monitoring. IT IS ESSENTIAL THAT A CAREFULLY PREPARED PROTOCOL, BASED ON CURRENT MEDICAL PRACTICES, BE FOLLOWED, PREFERABLY BY AN EXPERIENCED TEAM.

SUMMARY HIGHLIGHTS OF COMPLICATIONS (See also Current Medical Literature).

1. Technical

The placement of a central venous catheter should be regarded as a surgical procedure. One should be fully acquainted with various techniques of catheter insertion. For details of technique and placement

sites, consult the medical literature. X-ray is the best means of verifying catheter placement. Complications known to occur from the placement of central venous catheters are pneumothorax, hemothorax, hydrothorax, artery puncture and transection, injury to the brachial plexus, malposition of the catheter, formation of arteriovenous fistula, phlebitis, thrombosis and air and catheter emboli.

2. Septic

The constant risk of sepsis is present during administration of total parenteral nutrition. It is imperative that the preparation of the solution and the placement and care of catheters be accomplished under strict aseptic conditions.

Solutions should ideally be prepared in the hospital pharmacy under a laminar flow hood using careful aseptic technique to avoid inadvertent touch contamination. Solutions should be used promptly after mixing.

Storage should be under refrigeration and limited to a brief period of time, preferably less than 24 hours.

Administration time for a single bottle and set should never exceed 24 hours.

3. Metabolic

The following metabolic complications have been reported with TPN administration: Metabolic acidosis and alkalosis, hypophosphatemia, hypocalcemia, osteoporosis, hyperglycemia, and glycosuria, rebound hypoglycemia, osmotic diuresis and dehydration, elevated liver enzymes, hypo- and hypervitaminosis, electrolyte imbalances and hyperammonemia in children. Frequent evaluations are necessary especially during the first few days of therapy to prevent or minimize these complications.

Administration of glucose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma and death.

Pregnancy: Teratogenic effects.

Pregnancy Category C: Animal reproduction studies have not been performed with Aminosyn-HBC 7%. It is not known whether Aminosyn-HBC 7% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Aminosyn-HBC 7% should be given to a pregnant woman only if clearly needed.

Pediatric Use: Safety and effectiveness in children have not been established.

Geriatric Use: Clinical studies of Aminosyn-HBC 7% did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Drug Interactions

Because of its antianabolic activity, concurrent administration of tetracycline may reduce the potential anabolic effects of amino acids infused with dextrose as part of a parenteral feeding regimen.

Additives may be incompatible. Consult with pharmacist if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

ADVERSE REACTIONS

See ***WARNINGS*** and SPECIAL PRECAUTIONS FOR CENTRAL VENOUS NUTRITION.

Reactions secondary to the administration technique or the solution include febrile response, infection

at the injection site, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

Local reactions at the infusion site, consisting of a warm sensation, erythema, phlebitis and thrombosis have been reported with peripherally administered amino acid solutions, especially if other substances are also administered through the same site.

Generalized flushing, fever and nausea have been reported during peripheral administration of amino acids.

Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential.

If electrolyte supplements are required during peripheral infusions, it is recommended that additives be administered throughout the day in order to avoid possible vein irritation. Irritating additive medications may require injection at another site and should not be added directly to the amino acid infusate.

Phosphorus deficiency may lead to impaired tissue oxygenation and acute hemolytic anemia. Relative to calcium, excessive phosphorus intake can precipitate hypocalcemia with cramps, tetany and muscular hyperexcitability.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of fluid, electrolyte or metabolic imbalances re-evaluate the patient and institute appropriate corrective measures; see ***WARNINGS*** and ***PRECAUTIONS***.

DOSAGE AND ADMINISTRATION

Aminosyn-HBC 7%, Sulfite-Free, (an amino acid injection — high branched chain) is administered intravenously. The total dose depends upon daily protein requirements and the patient's metabolic and clinical response. The determination of nitrogen balance and accurate daily body weights, corrected for fluid balance, is probably the best means of assessing individual protein requirements.

While Recommended Dietary Allowances for oral protein are approximately 0.8 g/kg of body weight for the healthy adult, protein and caloric requirements in traumatized or malnourished patients may be substantially increased. To satisfy protein needs and promote positive nitrogen balance, the daily dosage level of amino acids for adult patients with adequate caloric intake is approximately 1.5 g/kg of body weight. Severely catabolic states may require higher dosage levels. Such higher doses must be accompanied by frequent laboratory evaluation. Fat emulsion may be administered to help meet energy requirements. Fat emulsion coadministration should be considered when prolonged parenteral nutrition is required in order to prevent essential fatty acid deficiency (E.F.A.D.). Serum lipids should be monitored for evidence of E.F.A.D. in patients maintained on fat-free total parenteral nutrition.

For optimum amino acid utilization, sufficient intracellular electrolytes (sodium, magnesium, and phosphate) should be provided. Approximately 60 to 180 mEq of potassium, 10 to 30 mEq of magnesium, and 10 to 40 mM of phosphate/day appear necessary to achieve optimum metabolic response. In addition, sufficient quantities of the major extracellular electrolytes (sodium, calcium and chloride) must be given. In patients with hyperchloremic or other metabolic acidoses, sodium and potassium may be added as the acetate or lactate salts to provide bicarbonate precursors. The electrolyte content of Aminosyn-HBC 7% must be considered when calculating daily electrolyte intake. Serum electrolytes, including magnesium and phosphorus, should be monitored frequently. If a patient's nutritional intake is primarily parenteral, trace metals and vitamins, especially the water-soluble vitamins, should also be provided.

Central Venous Nutrition: For severely catabolic, depleted patients or those who require long-term

parenteral nutrition, central venous nutrition should be considered. Total parenteral nutrition may be started with admixtures containing lower concentrations of dextrose; dextrose concentrations may be gradually increased to approximate estimated energy requirements as the patient's glucose tolerance increases.

In adults, strongly hypertonic admixtures of amino acids and dextrose may be safely administered only by continuous infusion through a central venous catheter with the tip located in the superior vena cava. A mixture containing 500 mL of Aminosyn-HBC 7% with 500 mL of concentrated dextrose supplemented with electrolytes, trace metals and vitamins may be administered over a period of approximately 8 hours. If prescribed administration rates should fall behind schedule, no attempt to "catch up" to planned intake should be made. In addition to meeting protein requirements, the administration is also governed by the patient's glucose tolerance, especially during the first few days of therapy. The daily intake of the amino acid/dextrose admixture should be increased gradually to the maximum required dose, based on serial determinations of urine and blood sugar levels. To prevent hyperglycemia and glycosuria, certain patients may require exogenous insulin in order to receive adequate calories from hypertonic dextrose. To prevent rebound hypoglycemia, a solution containing 5% dextrose should be administered when hypertonic dextrose infusions are abruptly discontinued.

Peripheral Parenteral Nutrition: For the moderately catabolic, depleted patient in whom aggressive central venous nutrition is not necessary, Aminosyn-HBC 7% may be given by peripheral vein with hypocaloric energy supplements. Dextrose in a final concentration of up to 10% and/or lipid emulsion may be administered.

Fat provides approximately 9 kcal/gram and in long-term therapy (more than 5-7 days) will prevent essential fatty acid deficiency. Parenteral fat emulsion may be administered simultaneously with amino acid-dextrose admixtures via a Y-type administration set to supplement caloric intake. Fat, however, should not provide more than 60% of the total caloric intake.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. COLOR VARIATION FROM PALE YELLOW TO YELLOW IS NORMAL AND DOES NOT ALTER EFFICACY.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

Aminosyn-HBC 7%, Sulfite-Free, (an amino acid injection — high branched chain) is supplied in 500 mL single-dose container (NDC No. 0409-4168-03) and 1000 mL single-dose container (NDC No. 0409-4168-05).

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]Protect from freezing.

Avoid exposure to light.

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Hospira, Inc., Lake Forest, IL 60045 USA	

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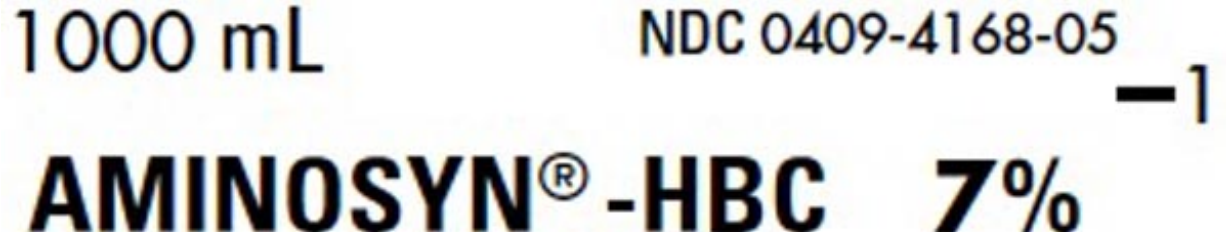

Sulfite-Free

An Amino Acid Injection

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EACH 100 mL CONTAINS: TOTAL AMINO ACIDS APPROX. 7 g. MAY CONTAIN HYDROCHLORIC ACID FOR pH ADJUSTMENT AND CONTAINS ACETATE FROM PROCESSING. **ESSENTIAL AMINO ACIDS/100 mL:** ISOLEUCINE 789 mg; LEUCINE 1576 mg; LYSINE (AS ACETATE SALT) 265 mg; METHIONINE 206 mg; PHENYLALANINE 228 mg; THREONINE 272 mg; TRYPTOPHAN 88 mg; VALINE 789 mg. **NONESSENTIAL AMINO ACIDS/100 mL:** TYROSINE 33 mg; ALANINE 660 mg; ARGININE 507 mg; GLYCINE 660 mg; PROLINE 448 mg; HISTIDINE 154 mg; SERINE 221 mg. **ELECTROLYTES (mEq/LITER):** ACETATE, 71. pH 5.2 (4.5 to 6.0)
623 mOsmol/LITER SPECIFIC GRAVITY = 1.02

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(01) 0 30409 41680 5 0

ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST, IF AVAILABLE. WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE.

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SINGLE DOSE CONTAINER. CONTAINS NO BACTERIOSTAT. DISCARD UNUSED PORTION. FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. STORE AT 20 TO 25°C (68 TO 77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.] AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. AVOID EXPOSURE TO LIGHT. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

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Rx ONLY

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CONTAINS DEHP

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Hospira

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WR-0306

TO OPEN — TEAR AT NOTCH

1000 mL

NDC 0409-4168-05

AMINOSYN®-HBC

7%

Sulfite-Free

AN AMINO ACID INJECTION

Each 100 mL contains: Total amino acids approx. 7 g. May contain hydrochloric acid for pH adjustment and contains acetate from processing. **Essential Amino Acids/100 mL:** Isoleucine 789 mg; leucine 1576 mg; lysine (as acetate salt) 265 mg; methionine 206 mg; phenylalanine 228 mg; threonine 272 mg; tryptophan 88 mg; valine 789 mg. **Nonessential Amino Acids/100 mL:** Tyrosine 33 mg; alanine 660 mg; arginine 507 mg; glycine 660 mg; proline 448 mg; histidine 154 mg; serine 221 mg. **Electrolytes (mEq/Liter):** Acetate, 71.

623 mOsmol/Liter pH 5.2 (4.5 to 6.0) Specific Gravity = 1.02

Single dose container. The overwrap is a moisture and oxygen barrier. Do not remove unit from overwrap until ready for use. Visually inspect overwrap for tears or holes. Discard unit if overwrap is damaged. Use unit promptly when overwrap is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

COLOR VARIATION FROM PALE YELLOW TO YELLOW IS NORMAL AND DOES NOT ALTER EFFICACY.

℞ only

LATEX

7 OTHER

F WR-0306 (6/06) PRINTED IN USA

AMINOSYN

isoleucine, leucine, lysine acetate, methionine, phenylalanine, threonine, tryptophan, valine, alanine, arginine, histidine, proline, serine, tyrosine, and glycine injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-4168
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOLEUCINE (UNII: 04Y7590D77) (ISOLEUCINE - UNII:04Y7590D77)	ISOLEUCINE	789 mg in 100 mL
LEUCINE (UNII: GMW67QNF9C) (LEUCINE - UNII:GMW67QNF9C)	LEUCINE	1576 mg in 100 mL
LYSINE ACETATE (UNII: TTL6G7LIWZ) (LYSINE - UNII:K3Z4F929H6)	LYSINE	265 mg in 100 mL
METHIONINE (UNII: AE28F7PNPL) (METHIONINE - UNII:AE28F7PNPL)	METHIONINE	206 mg in 100 mL
PHENYLALANINE (UNII: 47E5O17Y3R) (PHENYLALANINE - UNII:47E5O17Y3R)	PHENYLALANINE	228 mg in 100 mL
THREONINE (UNII: 2ZD004190S) (THREONINE - UNII:2ZD004190S)	THREONINE	272 mg in 100 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	88 mg in 100 mL
VALINE (UNII: HG18B9YRS7) (VALINE - UNII:HG18B9YRS7)	VALINE	789 mg in 100 mL
ALANINE (UNII: OF5P57N2ZX) (ALANINE - UNII:OF5P57N2ZX)	ALANINE	660 mg in 100 mL
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	507 mg in 100 mL
HISTIDINE (UNII: 4QD397987E) (HISTIDINE - UNII:4QD397987E)	HISTIDINE	154 mg in 100 mL
PROLINE (UNII: 9DLQ4CIU6V) (PROLINE - UNII:9DLQ4CIU6V)	PROLINE	448 mg in 100 mL
SERINE (UNII: 452VLY9402) (SERINE - UNII:452VLY9402)	SERINE	221 mg in 100 mL
TYROSINE (UNII: 42HK56048U) (TYROSINE - UNII:42HK56048U)	TYROSINE	33 mg in 100 mL

GLYCINE (UNII: TE7660XO1C) (GLYCINE - UNII:TE7660XO1C)	GLYCINE	660 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ACETIC ACID (UNII: Q40Q9N063P)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4168-03	12 in 1 CASE		
1		1 in 1 POUCH		
1		500 mL in 1 BAG		
2	NDC:0409-4168-05	6 in 1 CASE		
2		1 in 1 POUCH		
2		1000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019374	08/19/2010	

Labeler - Hospira, Inc. (141588017)

Revised: 3/2011 Hospira, Inc.